

Collaborative randomised controlled trial of trigger versus conventional ventilation in preterm infants with respiratory distress syndrome

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/10/2014	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.refer.nhs.uk/ViewRecord.asp?ID=193>

Contact information

Type(s)

Scientific

Contact name

Dr Harry Baumer

Contact details

Plymouth Hospitals NHS Trust
Derriford Hospital
Derriford Road
Plymouth
United Kingdom
PL6 8DH
+44 (0)1752 763450
harry.baumer@phnt.swest.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

C/6/16-04-94/BAUMER/F

Study information

Scientific Title

Study objectives

Objectives: To investigate the effects of Patient Triggered Ventilation (PTV) compared with conventional ventilation (Intermittent Mandatory Ventilation [IMV]) in preterm infants ventilated for Respiratory Distress Syndrome (RDS).

Setting: Twenty-two neonatal intensive care units.

Design: Subjects were 924 babies under 32 weeks gestation and within 72 hours of birth ventilated for RDS for less than 6 hours. Telephone randomisation to receive either PTV or IMV. Analysis on "intention to treat" basis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Neonatal diseases

Interventions

1. Trigger ventilation
2. Conventional ventilation

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. Death before discharge home or oxygen therapy at 36 weeks gestation
2. Pneumothorax whilst ventilated
3. Cerebral ultrasound abnormality nearest 6 weeks
4. Duration of ventilation in survivors

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/1994

Completion date

31/03/1998

Eligibility**Key inclusion criteria**

Infants of less than 32 weeks gestation, they are ventilated within 72 hours of birth, and have features compatible with respiratory distress syndrome

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

924

Key exclusion criteria

Babies with evidence of major congenital malformation or evidence of inhalational pneumonitis will be excluded

Date of first enrolment

01/11/1994

Date of final enrolment

31/03/1998

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Plymouth Hospitals NHS Trust

Plymouth

United Kingdom

PL6 8DH

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2000		Yes	No